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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,384	06/19/2001	Huda Y. Zoghbi	HO-P01492US2	5033

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/884,384	ZOGHBI ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed June 19, 2001 (Paper No. 2) has been entered. Claim 2 has been cancelled. Claims 11-24 have been newly added.

Claims 1 and 3-24 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 12, 16, and 19, drawn to a method of treating a neurodegenerative disease in a mammal by administering a chaperone or chaperone-like compound, classified in class 514, subclass 2.

II. Claims 4, 8, 11, 15, and 20, drawn to an *in vitro* compound screening assay, classified in class 435, subclass 4.

III. Claims 5, 9, and 10, drawn to an *in vivo* compound screening assay and transgenic mice expressing HDJ-2, classified in class 800, subclass 3.

IV. Claim 6, drawn to a method of treating a neurodegenerative disease in a mammal by administering a compound that increases the concentration of a chaperone in the neurological system, classified in class 514, subclass 1.

V. Claim 7, drawn to a method of treating a neurodegenerative disease in a mammal by administering a compound that enhances the activity of a proteasome in the neurological system, classified in class 514, subclass 1.

VI. Claims 13 and 14, drawn to a compound having chaperone activity, classified in class 514, subclass 1.

VII. Claim 17, drawn to an unspecified compound, no classification.

VIII. Claim 18, drawn to an unspecified compound, no classification.

IX. Claims 21 and 24, drawn to a method of treating a neurodegenerative disorder by administering a compound which suppresses ataxin-1 aggregation, classified in class 514, subclass 2.

X. Claims 22 and 23, drawn to an unspecified compound that suppresses ataxin-1 aggregation, no classification.

The inventions are distinct, each from the other because of the following reasons:

Inventions VI-VIII and X are patentably distinct, one from the other, because the inventions are drawn to distinct compositions that are structurally, chemically, biologically and functionally distinct. The compounds are not obvious one over the other. Thus, the compositions of the inventions of Groups VI-VIII and X are patentably distinct, each from the other.

Inventions I-V and IX are patentably distinct, one from the other, because the inventions are drawn to materially different methods that have different modes of operation, different functions, and different effects. The various methods of treating a neurodegenerative disease require different starting materials and different modes of operation. The method of the invention of Group I requires as starting materials a chaperone compound and a mammal having a neurodegenerative disease, whereas the method of the invention of Group IV requires as starting materials a compound that increases the concentration of a chaperone in the neurological system and a mammal having a neurodegenerative disease. The method of the invention of Group V requires as starting materials a compound that enhances the activity of a proteasome and a mammal having a neurodegenerative disease. The method of the invention of Group IX requires as starting materials a compound which suppresses ataxin-1 aggregation and an individual having

a neurodegenerative disorder. Thus, the methods of the inventions of Groups I-V and IX are patentably distinct, one from the other.

Inventions I-V and IX are patentably distinct from inventions VI-VIII and X because the inventions are drawn to distinct methods and compositions. Although the composition of the invention of Group VI can be used in the method of the invention of Group I, its use is not limited to *in vivo* administration, as it can also be used for *in vitro* assays. Although the composition of the invention of Group X can be used in the method of the invention of Group IX, its use is not limited to therapy, as it can also be used for *in vitro* assays.

Each of the inventions of Groups I-X requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to the implementation of therapeutic protocols which are not required for examination of the invention of Group II. The searches for the inventions of Groups I-X are not coextensive. Thus, search and examination of all 10 inventions in a single patent application constitutes a serious burden on the Examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tiffiany Tabb, whose telephone number is (703) 305-1238.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE BAKER
PATENT EXAMINER